

## **II. REMARKS/ARGUMENTS**

Applicants acknowledge that the finality of the previous Office Action has been withdrawn and that the submission of 4/19/04 has been entered, in view of the filing of the Request for Continued Examination in respect of this application. Applicants further wish to thank the Examiner for the opportunity to discuss this matter on May 19 and 20, 2004.

### **A. Summary of the Amendments**

The application still contains 29 claims.

Independent claim 1 has been amended in order to better define the subject matter being claimed.

Claim 7 has been amended for clarity, which finds support, for example, in paragraph [0017] of the application.

Claims 2-6, 8-15, 17-24 and 45-50 remain the same.

Claims 25-44, which had previously been withdrawn, have now been cancelled. The subject matter of these claims is now being pursued in co-pending divisional application 10/687,167.

### **B. Summary of Rejection and Reply**

#### **Claims 1-7, 9-15, 49 and 50**

In the Office Action, the Examiner has rejected claims 1-7, 9-15, 49 and 50 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,613,982 (hereafter

referred to as Goldstein) in view of U.S. Patent 5,171,273 (hereafter referred to as Silver) in further view of U.S. Patent 5,067,962 (hereafter referred to as Campbell)

In response to the Examiner's rejection, Applicants respectfully direct the Examiner's attention to part (b) of independent claim 1, as amended:

- An implant for connective tissue substitution in an animal, said implant comprising:
- (a) a pair of bone anchors;
  - (b) **at least one support filament joining said bone anchors at their proximal ends, said bone anchors having been joined with said support filament *ex vivo*; and**
  - (c) at least one matrix layer coating said support filament, wherein said matrix layer is in contact with said bone anchors;
- wherein said matrix layer is of sufficient thickness to allow for colonization by a cell and wherein said matrix layer is dehydrated or lyophilized prior to implantation.

Applicants respectfully submit that none of the references cited by the Examiner disclose, teach or suggest the subject matter recited in part (b) of amended claim 1. More specifically, neither Goldstein, Campbell nor Silver describe an implant for connective tissue substitution that has a support filament joining a pair of bone anchors at their proximal ends, the bone anchors having been joined with the support filament *ex vivo*.

Firstly, neither Goldstein nor Silver disclose a structure comprising a pair of bone anchors joined by a support filament. Instead, Goldstein describes a method of preparing transplant tissue that involves decellularizing a natural tissue (i.e. an *in vivo* prepared base structure) to produce a decellularized tissue matrix, and incubating that matrix in fibroblast cells in order to repopulate the matrix. In addition, Silver simply describes a tendon graft formed of cross-linked synthetic collagen fibers embedded in a non-crosslinked collagen matrix. Since neither Goldstein nor Silver disclose an implant comprising at least one support filament joining a pair of bone anchors at their proximal ends, the bone anchors having been joined with the support filament *ex vivo*, these references cannot satisfy part (b) of amended claim 1 emphasized above.

Secondly, Campbell does not teach a bone anchor-filament-bone anchor structure, the bone anchors having been joined with the support filament ex vivo. To the contrary, the implant described by Campbell includes a bone-ligament-bone structure that is harvested directly from a donor animal already, and as such this structure is prepared in vivo. Campbell further describes that the purpose of their implant is to "preserve intact a substantial portion of a first natural ligament-to-bone attachment structure of the donor animal" (lines 5-6 of the Abstract). As such, Applicants respectfully submit that not only does Campbell not teach the subject matter recited in part (b) of amended claim 1, but that Campbell actually teaches away from the implant recited in the instant claims as amended.

The Examiner's attention is directed to MPEP §2142, which indicates that "To establish a *prima facie* case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations." Since neither Goldstein, Silver nor Campbell disclose, teach or suggest teach the subject matter recited in part (b) of amended claim 1, Applicants respectfully submit that these references taken either individually or in combination, do not satisfy the requirements to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejection of independent claim 1 be withdrawn.

Claims 2-7, 9-15, 49 and 50 depend from independent claim 1, and as such incorporate by reference all the limitations contained therein. Therefore, for the same reasons as those presented above with respect to independent claim 1, Applicants respectfully request that the rejection of dependent claims 2-7, 9-15, 49 and 50 be withdrawn.

**Claims 8, 17-24 and 45-48**

Claims 8, 17-24 and 45-48 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Goldstein as modified by Silver and Campbell in further view of U.S. Patent 6,287,340 (hereafter referred to as Altman).

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In response, applicant respectfully submits that claims 8, 17-24 and 45-48 are dependent on independent claim 1 as amended, and as such incorporate by reference all the elements contained therein, including the subject matter of part (b) noted above, which is absent from Goldstein, Silver and Campbell as noted above. Applicant further submits that this subject matter is also absent from Altman.

Altman relates to a method of preparing an anterior cruciate ligament (ACL) via the growth of pluripotent stem cells in a matrix, an example of which is a gel of collagen type I. The cells are cultured within the matrix to encourage their growth and regeneration while subjecting the matrix to mechanical forces. It is evident that the key focus of Altman is the application of such mechanical force.

Applicants first wish to note that Altman also does not mention nor suggest a "support filament" as presently claimed. Thus applicant respectfully submits that the requirements to establish a *prima facie* case of obviousness have not been met. Further, Altman does not disclose a support filament joining a pair of bone anchors. As such, Altman does not disclose the subject matter of part (b) of amended claim 1.

In accordance with §2142 of the MPEP, in order to establish a *prima facie* case of obviousness, the combination of references cited by the Examiner must teach all the limitations found in the claim. Since all of the references cited by the Examiner fail to disclose the subject matter of part (c) of amended claim 1, and since claims 8, 17-24 and 45-48 incorporate by virtue of claim dependency all the

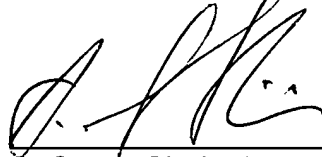
limitations of claim 1, Applicants respectfully submit that the combination of these references does not establish a *prima facie* case of obviousness for claims 8, 17-24 and 45-48. As such, applicant respectfully requests that the rejection of dependent claims 8, 17-24 and 45-48 be withdrawn.

### **CONCLUSION**

It is respectfully submitted that claims 1-15, 17-24 and 45-50 are in condition for allowance. Reconsideration of the rejections and objections is requested. Allowance of claims 1-15, 17-24 and 45-50 at an early date is solicited.

It is believed this responds to all of the Examiner's concerns, however if the Examiner has any further questions, she is invited to contact the undersigned. Further, If the Examiner does not consider that the application is in a form for allowance, an interview with the Examiner is respectfully requested.

Respectfully submitted,  
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